

Proposal for a Council Regulation amending Regulation (EEC) No 2309/93 as regards the budgetary and financial rules applicable to the European Agency for the Evaluation of Medicinal Products and access to the Agency's documents

(2002/C 331 E/09)

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(Submitted by the Commission on 17 July 2002)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 308 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament,

Whereas:

- (1) The provisions of Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products⁽¹⁾ should be harmonised with Council Regulation (EC, Euratom) No ... of ... on the Financial Regulation applicable to the general budget of the European Communities, and in particular Article 185 thereof.
- (2) The general principles and limits governing right of access to documents provided for in Article 255 of the Treaty have been laid down by Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents⁽²⁾.
- (3) When Regulation (EC) No 1049/2001 was adopted, the three institutions agreed in a joint declaration that the agencies and similar bodies should implement rules in line with that Regulation.
- (4) Appropriate provisions should therefore be included in Regulation (EEC) No 2309/92 to make Regulation (EC) No 1049/2001 applicable to the European Agency for the Evaluation of Medicinal Products, as should a clause guaranteeing a right of appeal against a refusal of access to documents.
- (5) It would be useful to clarify the rules for the conditions and procedures applying to the renewal of the term of office of the Executive Director and to harmonise the rules for all the Community bodies for which re-appointment is possible,
- (6) Regulation (EEC) No 2309/93 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EEC) No 2309/93 is amended as follows:

⁽¹⁾ OJ L 214, 24.8.1993, p. 1. Regulation as amended by Commission Regulation (EC) No 649/98 (OJ L 88, 24.3.1998, p. 7).

⁽²⁾ OJ L 145, 31.5.2001, p. 43.

1. Article 55(1) is replaced by the following:

'1. The Agency shall be under the authority of an Executive Director appointed by the Management Board, on a proposal from the Commission, for a period of five years, which, on a proposal from the Commission, may be extended for one further period not exceeding five years.'

(a) in paragraph 2, the fifth indent is replaced by the following:

'— for the preparation of the draft statement of estimates of the Agency's revenue and expenditure, and execution of its budget,'

(b) paragraph 3 is replaced by the following:

'Each year the Executive Director shall submit a draft work programme for the coming year to the Management Board for approval, making a distinction between the Agency's activities concerning medicinal products for human use and those concerning veterinary medicinal products.'

(c) Paragraph 4 is deleted.

2. Article 56(5) is replaced by the following:

'The Management Board shall adopt the annual report on the Agency's activities and transmit it by 15 June at the latest to the European Parliament, the Council, the Commission, the Economic and Social Committee, the Court of Auditors and the Member States.'

3. Article 57 is replaced by the following:

'Article 57

1. Estimates of all the revenue and expenditure of the Agency shall be prepared for each financial year, corresponding to the calendar year, and shall be shown in the budget of the Agency.

The revenue and expenditure shown in the budget shall be in balance.

2. The Agency's revenues shall consist of a contribution from the Community and fees paid by undertakings for obtaining and maintaining Community marketing authorisations and for other services provided by the Agency. The expenditure of the Agency shall include staff remuneration, administrative and infrastructure costs, and operating expenses, and expenses resulting from contracts entered into with third parties.

3. Each year, by 15 February at the latest, the Management Board, on the basis of a draft drawn up by the Executive Director, shall produce a statement of estimates of revenue and expenditure for the Agency for the following financial year. This statement of estimates, which shall include a draft establishment plan, shall be transmitted by the Management Board to the Commission by 31 March at the latest.

The statement of estimates shall be transmitted by the Commission to the European Parliament and the Council (hereinafter referred to as the "budgetary authority") together with the preliminary draft budget of the Communities.

4. The budgetary authority shall determine the appropriations available for the subsidy to the Agency.

5. The budgetary authority shall adopt the establishment plan for the Agency.

6. The Management Board shall adopt the Agency's definitive budget before the beginning of the budget year, adjusting it as necessary to the Community subsidy and the Agency's other resources.

7. The Executive Director shall implement the budget of the Agency.

8. The Commission's internal auditor shall exercise the same powers over the Agency as over Commission departments.

9. By 1 March at the latest following each financial year, the Agency's accounting officer shall communicate the provisional accounts to the Commission's accounting officer together with a report on the budgetary and financial management for that financial year. The Commission's accounting officer shall consolidate the provisional accounts of the institutions and decentralised bodies within the meaning of Article 128 of Regulation (EC, Euratom) No ... (*) (hereinafter "the general Financial Regulation").

10. By 31 March at the latest following each financial year, the Commission's accounting officer shall transmit the Agency's provisional accounts to the Court of Auditors, together with a report on the budgetary and financial management for that financial year. The report on the budgetary and financial management for the financial year shall also be transmitted to the European Parliament and the Council.

11. On receipt of the Court of Auditors' observations on the Agency's provisional accounts, pursuant to Article 129 of the general Financial Regulation, the Executive Director shall draw up the Agency's final accounts under his own responsibility and transmit them to the Management Board for an opinion.

12. The Management Board of the Agency shall deliver an opinion on the Agency's final accounts.

13. The Executive Director shall, by 1 July at the latest following each financial year, transmit the final accounts to the European Parliament, the Council, the Commission and the Court of Auditors, together with the Management Board's opinion.

14. The final accounts shall be published.

15. The Agency's Executive Director shall send the Court of Auditors a reply to its observations by 30 September at the latest. He shall also send this reply to the Management Board.

16. The European Parliament, on a recommendation from the Council acting by a qualified majority, shall, before 30 April of year N + 2, give a discharge to the Executive Director in respect of the implementation of the budget for year N.

17. The financial rules applicable to the Agency shall be adopted by the Management Board after the Commission has been consulted. They may not depart from the framework Financial Regulation adopted by the Commission under Article 185 of the Financial Regulation applicable to the general budget of the European Communities unless specifically required for the Agency's operation and with the Commission's prior consent.

(*) OJ L ...'

4. A new Article 63a is inserted:

'Article 63a

Regulation (EC) No 1049/2001 of the European Parliament and of the Council (*) shall apply to documents held by the Agency.

The Management Board shall adopt the arrangements for implementing Regulation (EC) No 1049/2001 within six months of entry into force of this Regulation.

Decisions taken by the Agency under Article 8 of Regulation (EC) No 1049/2001 may be appealed by means of a complaint to the Ombudsman or an action before the Court of Justice of the European Communities, under Articles 195 and 230 of the EC Treaty respectively.

(*) OJ L 145, 31.5.2001, p. 43.'

Article 2

This Regulation shall enter into force on the day following its publication in the *Official Journal of the European Communities*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.